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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,937	03/12/2001	Hirofumi Uchimiya	204323US0CIP	4787

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	13

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application N .	Applicant(s)	
	09/802,937	UCHIMIYA ET AL.	
	Examin r	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-18 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11,12 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it consists of two paragraphs. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of a discrepancy between the narrative and the sequence listing. At page 17 lines 20-27 SEQ ID NO:2 is described as a 1443 bp subfragment of SEQ ID NO:1. At page 4 of the sequence listing SEQ ID NO:2 is described as a 1440 bp DNA sequence. New matter should be avoided.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed March 12, 2001 and December 10, 2001, Paper Nos. 11 and 12, are attached to the instant Office action.

Document numbers 9-84587, 6-261767 and 3-277291 filed March 12, 2001 fail to comply with 37 CFR 1.98(a)(3) because they do not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Document numbers 9-84587, 6-261767 and 3-277291 have been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 10 is objected to because of the following informalities: the verb "consist" does not agree in number with the noun "DNA fragment". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a DNA fragment consisting of all or part of SEQ ID NO:1 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell, and to a DNA fragment consisting of all or part of SEQ ID NO:2 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell.

The specification describes a 4.3 kb DNA sequence of SEQ ID NO:1 obtained from rice that shares regions of homology with a previously reported adenylate kinase cDNA sequence (page 17 lines 3-18). The specification also describes a 1443 bp subfragment of SEQ ID NO:1 that corresponds to SEQ ID NO:2 and that exhibits promoter function in transgenic tobacco and

rice plants (page 17 lines 20-27; page 22; page 24). The specification does not describe or characterize any other fragments of SEQ ID NO:1, or any fragments of SEQ ID NO:2, or any fragments of SEQ ID NOS:1 or 2 wherein one or more bases has been deleted, added or replaced such that the fragment retains promoter function.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA fragment of SEQ ID NO:2 that functions to regulate the expression of an operably linked structural gene in plant cells, does not reasonably provide enablement for other isolated DNA fragments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a DNA fragment consisting of all or part of SEQ ID NO:1 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell, and to a DNA fragment consisting of all or part of SEQ ID NO:2 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell. The claims are also drawn to vectors comprising said DNA fragments, host bacteria transformed with said vectors, plant cells transformed with said vector and bacteria, plants regenerated from said plants cells, and seed from said plants.

The specification discloses a 4.3 kb DNA sequence of SEQ ID NO:1 obtained from rice that shares regions of homology with a previously reported adenylate kinase cDNA sequence (page 17 lines 3-18). The specification also discloses a 1443 bp subfragment of SEQ ID NO:1 that corresponds to SEQ ID NO:2 that exhibits promoter function in transgenic tobacco and rice plants when operably linked to a GUS reporter gene or a PAT selectable marker gene (page 17 lines 20-27; page 22; page 24). The specification does not disclose a promoter function for any other fragments of SEQ ID NO:1, or for any fragments of SEQ ID NO:2, or for any fragments of SEQ ID NOS:1 or 2 wherein one or more bases has been deleted, added or replaced.

Guidance for making and using the claimed invention is necessary for enablement because the ability of any particular nucleotide sequence to function as a promoter is highly unpredictable. Promoter sequence fragments or promoter sequences wherein one or more bases have been deleted, added or replaced cannot predictably be assumed to retain promoter function. This unpredictability originates in the mechanics of promoter function, which requires the presence of particular nucleotides in the sequence to mediate a specific promoter function. As a consequence, it is unpredictable whether a DNA fragment consisting of all or part of SEQ ID NO:1 or 2 or a DNA fragment wherein one or more bases of SEQ ID NO:1 or 2 has been deleted, added or replaced would retain promoter function, because it is unpredictable which sequence would retain all the particular nucleotides necessary to mediate promoter function.

For example, Kim et al. teach that various point mutations in the *nos* promoter can alter the presence or level of promoter activity in tobacco. (Plant Molecular Biology, 1994, Vol. 24, pages 105-117). Mutation of one or more nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity. These mutant promoter sequences differ from the native promoter sequence by only one to three nucleotides in a region that spans only 20 nucleotides, yet they vary greatly in the ability to

function as a promoter. This is because promoter function occurs through direct interaction between particular individual promoter nucleotides and the regulatory proteins that bind them.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed nucleotide sequences to use in order to regulate the expression of an operably linked structural gene.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10, and claims dependent thereon, are indefinite in the recitation of "functions to regulate expression of a structural gene viable in a plant or plant cell". First, it is unclear what is meant by a "viable" structural gene. The adjective "viable" is generally implies that something is "living" or "practicable". It is unclear how a DNA fragment would be "living" or "practicable". Second, it is unclear what is meant by "functions to regulate expression of a structural gene", as there are many different ways in which a DNA fragment may function to regulate expression of a structural gene, such as by functioning to promote the transcription of the coding sequence of a structural gene of which the fragment is a part, or by disrupting the expression of a structural gene by antisense or RNA inhibition.

Claims 7 and 16, and claims dependent thereon, are indefinite in the recitation of "transformed with the host bacterium". While bacteria may be used to facilitate the transformation of a plant cell with a recombinant DNA molecule, is unclear how a plant cell could be "transformed" with the bacterium itself.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 10 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 10, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claims 6, 9, 15 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 6, 9, 15 and 18 are drawn to seeds, but are not limited to seeds that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that

plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed seeds, it is unclear whether the claimed seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the seeds comprise in their genome the vector that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawai et al. (GenBank Accession No. D10334, 02 February 1999, and The Plant Journal, 1992, Vol. 2, No. 6, pages 845-854, Applicant's IDS).

The claims are drawn to a DNA fragment consisting of all or part of SEQ ID NO:1 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell, and to a DNA fragment consisting of all or part of SEQ ID NO:2 wherein one or more bases may be deleted, added or replaced so long as the fragment functions to regulate the expression of a structural gene viable in a plant or plant cell. The claims are also drawn to vectors comprising said DNA fragments, and host bacteria transformed with said vectors.

Kawai et al. teach a DNA fragment obtained from rice that consists of all or part of SEQ ID NO:1 wherein one or more bases may be deleted, added or replaced, and a DNA fragment consisting of all or part of SEQ ID NO:2 wherein one or more bases may be deleted, added or replaced (GenBank Accession No. D10334). The DNA fragment taught by Kawai et al. would inherently "regulate the expression of a structural gene viable in a plant or plant cell", because the DNA fragment taught by Kawai et al. meets the structural limitations of the claims, because the DNA fragment taught by Kawai et al. was obtained from plants and is known to be part of a adenylate kinase structural gene of rice, and because the claim does not limit the means by which the DNA fragment may "regulate expression". Kawai et al. also teach vectors comprising their DNA fragment, and host bacteria transformed with said vectors (page 851 Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-9 and 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. (GenBank Accession No. D10334, 02 February 1999, and The Plant Journal, 1992, Vol. 2, No. 6, pages 845-854, Applicant's IDS) in view of Rodriguez (US Patent 5,888,789 issued March 30, 1999).

The claims are drawn to plant cells transformed with the vector as defined in claims 2 or 11, and to plants regenerated from said plants cells, and to seed from said plants.

(1999) (1992)

The teachings of Kawai et al. are discussed *supra*. Kawai et al. also teach that expression of the adenylate kinase structural gene of rice from which their DNA fragment was obtained is induced by sucrose (page 851 Figure 8).

Kawai et al. do not teach plant cells transformed with the vector as defined in claims 2 or 11, or plants regenerated from said plants cells, or seed from said plants.

Rodriguez teaches rice plant cells transformed with a vector comprising a hormone-inducible rice RAmy1A promoter operably linked to a GUS reporter gene, plants regenerated from said plants cells, and seed from said plants (columns 33-36). Rodriguez also teaches that inducible promoters are useful in plants because they allow one to control when a heterologous protein is produced in a transgenic plant or plant cell (column 4 lines 1-19; column 5 lines 46-64).

Given that it was known in the art that inducible promoters are useful in plants because they allow for the control of heterologous protein production in transgenic plant and plant cells, and given that Kawai et al. teach a DNA fragment obtained from rice that consists of all or part of SEQ ID NO:1 wherein one or more bases may be deleted, added or replaced, and a DNA fragment consisting of all or part of SEQ ID NO:2 wherein one or more bases may be deleted, added or replaced, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use the DNA fragment taught by Kawai et al. to produce transgenic plants as taught by Rodriguez, without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
April 11, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638